# DEPARTMENT OF HEALTH AND HUMAN SERVICES and

### CENTERS FOR DISEASE CONTROL AND PREVENTION

### convene the

**ADVISORY COUNCIL FOR THE ELIMINATION OF TUBERCULOSIS** 

Atlanta, Georgia October 1-2, 2003

RECORD OF THE PROCEEDINGS

### **TABLE OF CONTENTS**

	<u>Page</u>
October 1, 2003	
Opening Session	1
CDC Update	
Report by the National Center for HIV, STD and TB Prevention Director	
Report by the Division of Tuberculosis Elimination Director	
USAID Expanded Response to Tuberculosis	
Status Report on TB Control in Jails	
Overview of TB and Corrections	
TB in City and County Jails: A Challenge to TB Elimination	12
Update on the CDC/Bureau of Immigration and	
Customs Enforcement Collaboration	15
CDC Activities for Foreign-Born TB	17
U.S./Mexico Binational TB Referral and Case Management Project	17
Electronic Disease Notification System	
Revised Technical Instructions for Civil Surgeons	
TB in Foreign-Born Persons in the United States and Canada	
Local and State Activities for Foreign-Born TB	
San Francisco	
Arizona	
ACET Discussion and Recommendations	28
October 2, 2003	
ACET Business	29
Update on Targeted Testing	
Update on the Revised TB Infection Control Guidelines	
TB Elimination Among U.SBorn African Americans	
DTBE Perspective	
SETB Workgroup Perspective	
Strategic Plan for TB Training and Education	
Closing Session	

## DEPARTMENT OF HEALTH AND HUMAN SERVICES CENTERS FOR DISEASE CONTROL AND PREVENTION

## Advisory Council for the Elimination of Tuberculosis October 1-2, 2003 Atlanta, Georgia

### **Minutes of the Meeting**

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) convened a meeting of the Advisory Council for the Elimination of Tuberculosis (ACET). The proceedings were held on October 1-2, 2003 at CDC's Corporate Square Facility, Building 8, in Atlanta, Georgia.

### **Opening Session**

Dr. Masae Kawamura, the ACET Chair, called the meeting to order at 8:35 a.m. on October 1, 2003. She welcomed the attendees to the proceedings and opened the floor for introductions. The following individuals were present to contribute to the discussion.

#### **ACET Members**

Dr. Masae Kawamura, Chair

Dr. Wafaa El-Sadr

Dr. Michael Fleenor

Dr. David Gonzales

Ms. Harriett Gray

Ms. Sara Loaiza

Ms. Eileen Napolitano

Dr. Stephen Puentes

### **Ex Officios and Liaisons**

Dr. William Baine (AHRQ)

Dr. Eric Blank (APHL)

Dr. Amy Bloom (USAID)

Dr. Henry Blumberg (IDSA)

Dr. Raymond Chinn (HICPAC)

Ms. Fran Dumelle (ALA)

Dr. Miguel Escobedo (U.S./Mexico BHC)

Ms. Caroline Freeman (OSHA)

Dr. Fred Gordin (ATS)

Dr. James McAuley (CCCS and IDSA)

Dr. Sheldon Morris (FDA)

Dr. Lee Reichman (ACCP)

Dr. Randall Reves (NTCA)

Dr. Gary Roselle (VA)

Ms. Rachel Stricof (APIC)

Dr. Diana Schneider (DIHS)

Dr. Eva Solorzano (U.S./Mexico BHC)

Ms. Terry Tannebaum (IUATLD)

Dr. Michael Tapper (SHEA)

Mr. Jonathan Van Geest (AMA)

Dr. Theresa Watkins-Bryant (HRSA)

### **Designated Federal Official**

Dr. Ronald Valdiserri, Executive Secretary

### **CDC Representatives**

Dr. Harold Jaffe, NCHSTP Director

Dr. Kenneth Castro, DTBE Director

Mr. John Anderton

Mr. Subroto Banerji

Mr. James Barrow

Dr. Jose Becerra

Ms. Thena Durham

Ms. Mollie Ergle (Contractor)

Ms. Maria Fraire

Ms. Paulette Ford-Knights

Ms. Maryam Haddad

Dr. Paul Jensen

Dr. John Jereb

Ms. Elizabeth Kalayil

Dr. Dolly Katz

Ms. Ann Lanner

Dr. Mark Lobato

Dr. Susan Maloney

Ms. Lilia Manangan

Mr. Scott McCoy

Dr. Scott McNabb

Ms. Jane Mezoff

Dr. Mary Naughton

Dr. Thomas Navin

Dr. Richard O'Brien

Mr. Tony Perez

Mr. Paul Poppe

Dr. Noreen Qualls

Dr. Eileen Schneider

Ms. Margie Scott-Cseh

Ms. JoAnn Shoup

Ms. Karlie Stanton

Dr. Zachary Taylor

Dr. Ed Thompson

Dr. Wanda Walton

### **Guests**

Dr. Stephanie Bailey (Tennessee DOH)

Ms. Carol Pozsik (TB Consultant)

Mr. John Seggerson (NCET)

Ms. Elizabeth Williams (Arizona DHS)

Dr. Ronald Valdiserri, the ACET Executive Secretary, also welcomed the attendees to the meeting. He was pleased to announce that new *ex officios* and liaisons are representing three organizations for the first time in ACET's history: Ms. Duiona Baker of the Substance Abuse and Mental Health Services Administration; Dr. William Baine of the Agency for Healthcare Research and Quality; and Drs. Miguel Escobedo and Eva Solorzano of the U.S./Mexico Border Health Commission. He explained that while federal officials serve as *ex officios*, representatives of professional non-governmental organizations (NGOs) serve as liaisons. Both categories are non-voting, but input from these representatives is extremely important to ACET.

Dr. Valdiserri explained ACET's function and operation as mandated by federal law. All comments made during ACET's deliberations are a matter of public record since meetings are open to the media and general public. All members must complete and submit financial disclosure forms. Members who received waivers for issues that the CDC Committee Management Office identified as a conflict of interest should recuse themselves from voting or participating in that particular discussion.

### **CDC Update**

Dr. Ed Thompson, the CDC Deputy Director for Public Health Services, described the Futures Initiative. Under this activity, CDC re-examines its role and function in the broader public health system every ten years to ensure that all programs are properly positioned to fulfill responsibilities in the future. One of the most important components of the Futures Initiative is input from external partners. Questionnaires are administered and discussion groups are convened to determine products and services external partners need or want from CDC. CDC then uses this feedback to make strategic decisions that will guide programs over the next decade.

Information gathered during this process may not be compiled into a report; instead, the most important outcome of the Futures Initiative is an understanding of CDC's role and function in the future direction of public health. Dr. Thompson invited ACET to obtain additional information about the Futures Initiative from the CDC web site. Extensive involvement in this activity by both internal and external sources will significantly improve the overall process and results.

### Report by the National Center for HIV, STD and TB Prevention (NCHSTP) Director

Dr. Harold Jaffe's update covered the following areas. First, Dr. Hazel Dean was appointed as the Office of Health Disparities Director. Her primary responsibility will be to expand NCHSTP's activities related to correctional, women's and minority health. Dr. Jonathan Kaplan's position as the Division of AIDS, STD and TB Laboratory Research Director will be vacant after his transfer to the Global AIDS Program (GAP) on January 1, 2004. CDC is asking ACET to suggest potential candidates for the search committee to consider.

The HIV, TB and STD laboratories were merged and administratively transferred from the National Center for Infectious Diseases (NCID) to NCHSTP on October 1, 2003 to better integrate laboratory services and other NCHSTP programs. Because each laboratory will maintain its respective budget, the transfer will not result in a decrease or increase to the NCHSTP budget. Second, CDC established a new Office of Public Health Research to coordinate systematic reviews and strengthen the quality of funded research projects. The current policy that requires external review of at least 33% of CDC's research projects will be expanded to 66% in 2004 and 100% in 2005.

Third, both the House and Senate passed the FY'04 budget; CDC will operate under a continuing resolution for two months. The House markup of \$136.6 million for TB

reflects a \$1 million increase from the FY'03 appropriation. The House expressed concern that 66% of TB cases are among African Americans and foreign-born populations. Unique programs in Florida and Oklahoma that utilize faith-based organizations to prevent and control TB among foreign-born populations were noted in the House comments. CDC was urged to support these models. The Senate markup reflects an additional \$1 million for TB for an overall increase of \$2 million. The Senate language and recommendations were similar to those made by the House.

NCHSTP is anticipating roughly level funding for STD and domestic HIV. Dollars for international AIDS represent the largest increase for NCHSTP; the President has requested an increase of \$110 million for prevention of mother-to-child HIV transmission. The provision of \$50 million from the House and \$110 million from the Senate will be resolved in Committee discussions. Fourth, the Comprehensive TB Elimination Act of 2003 was introduced and calls for an FY'04 appropriation of \$528 million for CDC's TB elimination program. A companion bill was introduced in the Senate that would authorize \$235 million. Each bill was referred to its respective Committee.

### Report by the Division of Tuberculosis Elimination (DTBE) Director

Dr. Kenneth Castro's update covered the following areas. First, the possibility of NCHSTP addressing non-tuberculous mycobacteria in collaboration with NCID is currently being explored. DTBE will seek guidance from ACET on this issue as the discussions progress. Second, the CDC Management Analysis and Services Office approved the reorganization of DTBE in June 2003. In general, international activities were formalized into a branch and DTBE branches were renamed to more accurately reflect the respective functions. In particular, activities and projects being performed by the branches are detailed below.

The Communication and Behavioral Studies Branch (CEBSB) sponsored the TB Education and Training Network on August 12-15, 2003 with ~100 participants from TB programs, federal agencies, hospitals, universities, Model TB Centers and the American Lung Association (ALA). The sessions focused on skill building and networking opportunities. CEBSB will host the annual the TB Program Manager's Course on October 20-24, 2003 in Atlanta, Georgia. CEBSB will convene the Behavioral and Social Science Forum on December 10-11, 2003 to identify and prioritize TB behavioral science research gaps and create a mechanism for communication between NGOs and health departments at national, state and local levels.

CEBSB recently updated the TB Education and Training Resource Guide. The document is available online and is being developed as a searchable database.

CEBSB posted companion slides to the TB treatment guidelines on the CDC web site. CEBSB is responsible for three task orders under the TB Epidemiology Studies Consortium (TBESC). Focus areas include barriers to treatment and adherence for latent TB infection (LTBI) and active TB among African Americans and knowledge, skills and abilities among private providers who primarily serve foreign-born populations. The Clinical and Health Systems Research Branch (CHSRB) recently signed a memorandum of understanding with the Health Resources and Service Administration (HRSA) AIDS Bureau to assess the completeness of TB screening and services among important target populations.

CHSRB will convene the next TB Trials Consortium (TBTC) meeting on October 20-22, 2003 in Atlanta, Georgia. Study 27 under TBTC was approved as a Phase II evaluation of moxifloxacin versus ethambutol during the initial phase of TB treatment. CHSRB received approval to expand TBTC to new foreign sites in Durban, South Africa; Barcelona, Spain; and Kampala, Uganda. Two of the three foreign sites will be able to enroll patients in the ongoing assessment of rifapentine as a once-weekly regimen for LTBI treatment. CHSRB recently completed an external review of data management and statistical support for TBTC. These results will be shared with ACET.

CHSRB is continuing field evaluations of the QuantiFERON (QFT) TB test approved by the Food and Drug Administration (FDA) as well as assessments of "QFT Gold" to examine potential use of the drugs in TB clusters, outbreaks and selected contact investigations. The Field Services and Evaluation Branch (FSEB) will implement pilot projects to intensify TB prevention and control interventions targeting U.S.-born African Americans. Chicago, Georgia and South Carolina are the successful grantees of this effort. The pilot projects were developed in direct response to recommendations by ACET and the Southeast TB Workgroup for CDC to analyze excess TB rates in U.S.-born African Americans. FSEB is collaborating with the Office of Health Disparities and the Office of Minority Health to contact other minority groups. Efforts are being made to establish TB booths at existing meetings to highlight the problem of TB in U.S.-born racial/ethnic minority groups.

FSEB has lead responsibility for developing the TB Patient Management module for the National Electronic Disease Surveillance System (NEDSS) in partnership with the Information Technology and Statistics Branch (ITSB). FSEB is closely collaborating with the Division of Global Migration and Quarantine (DGMQ) to develop the TB electronic disease notification system. FSEB and TB control partners are creating appropriate guidance to re-compete the TB cooperative agreement in FY'05 and place more emphasis on TB health disparities, foreign-born populations and other special groups. Efforts will be made to distribute funds in the FY'05 cooperative agreement based on disease burden and local needs.

The International Research and Programs Branch (IRPB) has 14 full-time employees and eight international country assignments. IRPB will heavily rely on support from the U.S. Agency for International Development (USAID) to focus on foreign-born TB in the United States from Mexico, Vietnam and the Philippines; TB/HIV co-infection in collaboration with GAP; multi-drug resistant (MDR) TB from Peru, Russia, Baltics and South Africa; and an expansion of directly observed treatment short-course (DOTS) in 22 high-burden countries in partnership with the World Health Organization (WHO). IRPB recently responded to a request by HHS to perform a technical review of TB proposals submitted to the Global Fund for AIDS, TB and Malaria. IRPB is a member of the Coordinating Board and various workgroups of the Stop TB Partnership.

ITSB supports the import utility or transitional software for the TB Information Management System (TIMS) and also provides statistical support for TBTC and TBESC. ITSB has lead responsibility for developing and supporting software applications within DTBE; supporting local area networks; and obtaining the new HHS security certification and accreditation for web pages and other information technology systems. The Surveillance, Epidemiology and Outbreak Investigations Branch (SEOIB) has lead responsibility for the transition of the TB surveillance system from TIMS to NEDSS in collaboration with ITSB. SEOIB posted the 2002 TB surveillance slide set on the CDC web page with new figures and tables to illustrate ten-year race/ethnicity trends and birth countries in the top 30 WHO regions; the companion summary is forthcoming.

SEOIB developed a manuscript to address TB in the Southeastern United States in response to ACET's recommendation. The article was cleared by DTBE and will be published in the *Morbidity and Mortality Weekly Report (MMWR)*. SEOIB coordinates TBESC activities and responded to requests for TB epidemiologic assistance from January-September 2003. SEOIB provided four epi-aids and made three onsite support visits. SEOIB has lead responsibility for a workgroup that is developing a solid surveillance system for adverse events associated with LTBI treatment. The workgroup was established in direct response to recent hepatitis cases and deaths associated with a two-month regimen of rifampin and pyrazinamide. Updates on the workgroup's progress will be presented to ACET. SEOIB is contributing to the Biotechnology Engagement Program. The initiative is sponsored by HHS to involve biological weapons scientists in other public health fields, particularly the development of surveillance projects in Armenia and the Republic of Georgia.

ACET focused on the "pitiful" TB budget and actions the members can take to secure additional funding. Each DTBE branch has specific responsibilities, but these activities cannot be completed with a 1% increase in the TB budget. The decline of TB rates in most states has played a major role in decreased funding and less advocacy for TB at the local level. The inability to replace the aging TB workforce by educating and training

new staff is another outcome of the insufficient budget. CDC clarified ACET's abilities and restrictions. On the one hand, ACET can voice concerns about the inadequate TB budget by communicating with the HHS Administration, making formal statements on the record, or recommending strategies to address TB activities that are adversely impacted.

Individual members representing themselves or their specific organizations can serve as CDC external partners by educating elected local officials and Congress to raise awareness about the TB problem and leverage funding. On the other hand, ACET cannot lobby to increase the TB budget because members serve as special government employees. CDC acknowledged that several TB activities are adversely impacted by the inadequate budget. Dollars for targeted testing and LTBI treatment will soon be redistributed because a basic cost-of-living increase is not covered by the minuscule amount of available funding. The FY'05 cooperative agreement will most likely have a weaker emphasis on targeted testing to ensure that persons with TB and their contacts are identified and treated.

TB research can barely be sustained; major breakthroughs for new tools development cannot be made with the current level of resources. CDC is not directly supporting global TB activities other than in-kind contributions of staff salaries; instead, heavy reliance is placed on USAID's global TB program. However, USAID policy may prohibit the program from being implemented in Vietnam or other high-burden countries. The Federal TB Task Force (FTBTF) formally responded to the Institute of Medicine (IOM) recommendations outlined in the *Ending Neglect* report. FTBTF acknowledged the need to formally review adverse effects the budget has on specific TB activities and propose action steps. Workgroups on programmatic issues, research and global TB are being established in this effort. The FTBTF response was approved by HHS in August 2003 and has been distributed to ACET.

ACET took actions and made suggestions in follow-up to the clarification of its role and the impact of the budget on TB activities. At the group level, ACET will write a letter to the HHS Secretary requesting a meeting with him or his designee to discuss inadequate TB funding. ACET made a formal statement on the record to emphasize that the budget is adversely impacting TB elimination strategies. Current funding cannot support targeted testing, TB workforce training and education, and an expansion of research to advance TB diagnostics and drug development. ACET should use the FY'05 cooperative agreement to establish a sound basis for increased funding. The FTBTF report should be reviewed and the needs of states should be identified in this effort.

At the individual level, members should use media articles on TB outbreaks to demonstrate to local TB programs that the disease continues to be a problem in the

United States. Members should attend a course offered by the National Coalition for the Elimination of Tuberculosis (NCET) in November 2003 in Newark, New Jersey. The course will be designed to strengthen advocacy skills for communicating with policymakers and the media. Members should participate in the Futures Initiative to emphasize to CDC centers beyond NCHSTP the value and need for TB elimination. This opportunity can also be used as a platform for members to voice concerns about CDC's weak emphasis on TB.

### **USAID Expanded Response to Tuberculosis**

Dr. Amy Bloom is the ACET *ex officio* for USAID. She described the agency's global TB program to expand the DOTS strategy through partnerships and capacity building. USAID's goal is to contribute to the global reduction of morbidity and mortality associated with TB. The goal will be achieved by enhancing country capacity to prevent and cure TB and achieving global target rates of 70% for case detection and 85% for treatment success. USAID focuses on TB because of its significant development and economic implications, status as a serious global public health threat, impact on the survival of persons living with HIV/AIDS, and consequences for women's health.

Globally, 155 of the 210 countries that are members of WHO are implementing DOTS. Among smear-positive patients, the treatment success rate is 82% in DOTS areas and 28% in non-DOTS areas. Current data show that 61% of the population is "covered" by DOTS, but actual coverage varies considerably among programs. Only 32% of estimated smear-positive cases were notified in 2001. In 2001, Vietnam was the only high-burden country to achieve targets for case detection and cure established by WHO. Challenges to global TB control include a lack of adequately trained workers and few international TB experts, HIV co-infection, drug resistance, inadequate drug supplies for all infectious patients, insufficient technology for diagnosing and managing TB, and limited cooperation with private providers.

Of USAID's \$1.56 billion health budget, 12% is allocated to infectious diseases. USAID's TB budget dramatically increased from \$0 in 1998 to current funding of \$75.4 million. USAID currently allocates \$60.4 million of the total TB budget for DOTS expansion at the country level: 29% to the Bureau for Global Health (BGH), 22% to Asia and the Near East, 18% to Africa, 16% to Latin America, and 15% to Eastern Europe and Eurasia. BGH allocates \$3 million to the Global Drug Fund, \$2 million to TB private voluntary organizations and \$1.2 million for country-level technical assistance on drug management issues. The bulk of USAID funds go to field missions in various countries.

USAID collaborates directly with the government in some countries, but also utilizes NGOs, particularly where a direct partnership with the government is not possible. NGO support is also critical because USAID is prohibited from paying salaries of government workers. USAID has established several criteria to select countries to implement the global TB program. Countries of greatest need are defined by a high incidence of TB, large number of cases, significant contribution to the global TB burden, high prevalence of HIV/AIDS, or the potential for the development of resistant disease.

USAID's decision-making process is also influenced by the feasibility of implementing the global TB program from technical and managerial perspectives, level of political and government commitment, country and donor capacity, and foreign policy considerations. USAID programs are currently being implemented in 39 countries. In general, several programmatic concepts are essential to USAID's expanded response, including a concentration on country level activities; an expansion of global, national and private partnerships; capacity building of USAID staff, consultants, the local workforce and other partners; and communication and advocacy.

The expanded response will be achieved through a number of specific activities. To expand and strengthen DOTS, laboratories will be renovated and necessary equipment will be provided; national plans for DOTS expansion prepared; norms and guidelines developed and disseminated; technical assistance provided for procurement and management of TB drugs; programs monitored and supervised; health personnel trained; and information systems standardized and improved. To increase and enhance human resource capacity, health personnel at all levels will be trained, training materials developed and disseminated, support provided to prepare national plans for human resource development, and the pool of TB consultants expanded.

To develop and disseminate new tools and approaches, clinical trials and the assessment of new treatment regimens will be supported, emphasizing rapid, accurate, and affordable diagnostics and regimens. In addition, operations research will be conducted to improve access and quality, identify successful community-based approaches, strengthen public/private partnerships, focus on social, economic and behavioral factors, design incentives, and create cost-effective approaches to MDR-TB and HIV-TB co-infection. USAID is also committed to improving and expanding technical expertise in pharmaceutical management systems, advocating for the incorporation of drug management systems into DOTS programs, and providing technical assistance to Stop TB and the Global Drug Fund through assessments of national capabilities, workshops, and training sessions.

Adaptation of the DOTS program to specific issues is critical to ensuring appropriate implementation. In the area of MDR-TB, epidemiological analyses and modeling will be performed and DOTS Plus projects for MDR-TB will be piloted, and where successful,

expanded. TB drug resistance surveys will be administered and laboratory capacity to monitor resistance enhanced. In the area of HIV/TB, efforts to adapt the DOTS strategy will include strengthening coordination between TB and HIV/AIDS programs, promoting voluntary counseling and testing with linkages to TB services, and testing new service delivery approaches.

USAID is implementing its expanded response in collaboration with a number of key partners, particularly the TB Coalition for Technical Assistance (TBCTA). CDC, ALA, the American Thoracic Society (ATS), the International Union Against TB and Lung Diseases, WHO, and the Royal Netherlands Tuberculosis Association are the six TB organizations in this unique partnership. TBCTA provides technical assistance to key countries and USAID missions through country assessments, strategic planning, leadership development, capacity building and operations research. TBCTA also identifies TB experts to provide technical assistance to augment in-country expertise. USAID's expanded response and the efforts of its partners have already resulted in DOTS improvements in India, Russia and South Africa.

ACET pointed out that many advocacy groups, local health departments as well as community- and faith-based organizations in the United States are willing to become involved with USAID's expanded response for the DOTS strategy. USAID and TBCTA should make strong efforts to outreach to these groups. Dr. Bloom noted that USAID is helping a number of organizations optimize their ability to contribute their expertise.

### Status Report on TB Control in Jails

Overview of TB and Corrections. Dr. James McAuley is the ACET liaison for correctional health. He noted that corrections is the second most important issue to address for TB control and elimination in the United States. In February 2000, two million persons were in U.S. prisons and jails; this figure surpassed all other countries in the world. By the end of 2002, ~6.7 million American adults were in jail or under supervision. Over the course of one year, ~10 million persons are booked into 3,365 U.S. jails. Data show a disproportionate incarceration rate among poor minority populations in U.S. jails. The rate of 700/100,000 among black non-Hispanics in 1990-2000 was seven times higher than white non-Hispanics.

Because incarcerated persons are the only U.S. population with a Constitutional right to receive health care, jail-based interventions can have a high public health impact. Jail serves as the primary health care source for the majority of detainees. Many poor and disenfranchised persons admitted to jails are frequently at high risk for HIV/AIDS, TB, STDs, hepatitis, food borne outbreaks, mental illness, violence, substance abuse or chronic diseases. According to a national survey in 1992-1993, the TB infection rate

was 10% in U.S. jails and prisons and the TB disease rate was 121/100,000. The rate is comparable to many developing countries. During this time, 43 TB cases were reported among jail and prison officers with two having MDR-TB.

From 1991-1993, California, New Jersey and New York state health departments reported a 7- to 11-fold relative risk increase of TB case rates among prison inmates versus the general population. The published literature contains several studies documenting TB in prisons and jails. The data show that time spent in a New York City jail was a TB risk factor; TB was undetected in prisons; an MDR-TB outbreak occurred in a New York prison; TB outbreaks were detected when HIV-infected persons were housed in the same area in California, South Carolina and Texas jails; 39% of ~35 prisons or jails were associated with prevalent TB in the United States; and ~25% of Florida TB cases were related to jail time within the last two years.

In another published study, active TB was diagnosed in 38 detainees or inmates and five guards over a three-year period in a Tennessee jail. Of community TB cases in this jurisdiction, 43% had been incarcerated. TB screening was limited to intake questions and a tuberculin skin test (TST) on day ten. At the local level, the 100-acre Cook County Jail (CCJ) in Chicago, Illinois is the largest single-site detention facility in the United States and is located in the third largest metropolitan area in the country. CCJ has an average daily population of ~11,000, an average yearly admission of 100,000 and an average daily intake of 300-350. Approximately 66% of detainees are released to the community. CCJ provides health care through the Cook County Bureau of Health Services.

Upon admission to CCJ, tests and mini-film chest radiographs are administered to screen for medical problems, mental illness, STDs and pregnancy. Because CCJ is considered to be a premiere jail system, its comprehensive screening program is not the standard in other U.S. jails. Efforts must be made to quickly deliver TB care since 50% of detainees are released by day nine of incarceration and only 16% remain in CCJ by day 60. CCJ reviews mini-film chest radiographs of detainees on a daily basis; a large chest radiograph is then taken to confirm abnormal results. The total cost of mini-film chest radiograph screening is estimated to be \$3.12 per inmate. To rule out TB for 20-23 cases detected per year, CCJ isolates ~300 persons per year in its state-of-the-art TB isolation unit with negative flow and 15 beds. CCJ's TB case rate of 23/100,000 is substantially higher than the city of Chicago's rate of 11/100,000.

Strong efforts are made to avoid TB exposure by isolating any case that has had contact with CCJ for 18 hours or more. Unlike other correctional settings, CCJ detainees have a low rate of HIV infection of only 2.5%. In terms of LTBI, CCJ stopped the two-month rifampin/pyrazinamide (2RZ) regimen due to toxicity issues. Skin testing was discontinued due to rapid turnover among detainees. Only 30,000 of 100,000 skin

tests could be read; only 3,000 tests could be evaluated for eligibility of LTBI treatment; only 300-500 detainees could be started on therapy; and only 11% of detainees who started a six-month course of isoniazid (INH) completed therapy.

Of all CCJ detainees, 9.5% were TST-positive; 18% were positive based on current QFT-TB tests; and 66% completed the 2RZ regimen. CCJ determined that replacing skin tests with the QFT-TB test is feasible in a jail setting, but six- or nine-month LTBI treatment is more difficult. Instead, test results should be given to the prison if the detainee is sentenced or to the patient if the individual is released. CCJ realizes that LTBI treatment is more likely to be completed in prisons since these populations are more stable than jail detainees. In 2003, CCJ stopped all short-course LTBI treatment with rifampin and pyrazinamide based on CDC's recommendation.

Since CCJ was unable to document skin test conversion in jail officers, the current system is considered to be relatively successful. However, CCJ acknowledges that data are flawed in some areas because the previous system was paper- rather than computer-based and the turnover rate among officers is high. In a match of TB registries for CCJ and Cook County for the years 1995-2001, CCJ found that 163 active cases had passed through the jail, but were not active at the time. Although large urban jails have relatively low TB case rates, this population still presents a prime opportunity to identify lost cases or those eligible for treatment to prevent future cases.

TB in City and County Jails: A Challenge to TB Elimination. Dr. Mark Lobato of DTBE described CDC's recent evaluation study of TB control measures in jail systems. CDC's national surveillance data show that TB cases in all types of correctional facilities have been decreasing since 1994. However, TB rates among detainees are still five to ten times higher than the local population. State prisons account for 25% of TB cases, while jails account for 55%. Correctional facilities in the northeast, south and West Coast of the United States report the highest TB burden; California and Texas account for nearly 50% of cases alone. TB risk factors are much more prevalent among inmates than non-inmates, particularly homelessness, excess alcohol use, and injecting or non-injecting drug use.

In response to several TB outbreaks in prisons among inmates, correctional staff and community members, CDC released guidelines on the prevention and control of TB in correctional facilities in 1996. In 2000-2001, CDC conducted a study to determine the extent to which the national recommendations were being implemented; assess the extent of collaboration between correctional facilities and health departments; and identify barriers to collaboration. CDC randomly selected 20 large jail systems with an average daily population of  $\geq 1,500$  inmates and a TB case rate greater than or equal to the national average. Data collection was accomplished with site visits and questionnaires to jail medical directors and local health department TB controllers.

The evaluation study focused on key TB areas outlined in the 1996 guidelines; the results are as follows. For TB screening and diagnosis, the jails had adequate written policies, but failed to screen for symptoms. Skin testing and chest x-rays were not administered in a timely fashion. One jail conducted an observational study to determine whether correctional officers correctly asked TB questions during intake of 97 inmates. Questions about current or past TB and frequent cough, fevers or night sweats were correctly asked for only 6%-29% of the 97 inmates.

For <u>high-risk inmates</u>, HIV counseling and testing with LTBI and chest x-ray screening were inadequate. Less than 50% of jails in the evaluation study had policies to offer HIV testing to TST-positive patients. At least 33% of medical records did not chart HIV status for co-infected inmates. More than 25% of jail systems did not require chest x-rays of known HIV-positive patients. Lengthy delays in obtaining chest x-rays were routine in the jails.

For <u>TB environmental controls and isolation</u>, ≥14% of suspects who were evaluated for TB were not isolated, while 44% were not isolated within a 24-hour period. Airborne infection isolation rooms (AIIR) were inadequately used and monitored. TB suspects or cases were sometimes held in cells without ultraviolet lights, a filtration system or any other environmental controls in 33% of jails. Of 12 jails in the study with an onsite AIIR, six did not conform to monitoring guidelines when the room had a TB suspect.

For <u>TB contact investigations</u>, 19 of the 20 jails in the study performed investigations for confirmed TB cases, but 66% lacked written protocols for contact investigations. Most jails held inmates in isolation until sputum smear results were returned. The majority of inmates were found to be smear-negative and culture-positive. Inmates with smearnegative results are released into the general jail population.

For <u>TB information systems and program assessment</u>, >33% of jail systems had no paper or electronic system and only a few had an electronic database. Only 14% of TB cases and suspects had complete medical data outlining the results of skin tests, chest x-rays, sputum tests and treatment.

For collaboration between jails and health departments, ~50% of jails collaborated with health departments in the development of TB policies and protocols, discharge planning, TB staff training and environmental controls. Only ~25% of jails collaborated with health departments in TB education for inmates and quality assurance for screening, diagnosis and therapy. Approximately 33% of jails reported effective collaboration. The jails and health departments in the study rated insufficient funding and staffing as the top two barriers to collaboration. Other challenges included lack of

communication, administrative structures of the two institutions, and competing priorities of public security for jails and public health for health departments.

Effective collaboration between jails and health departments was more likely to occur if formal mechanisms were established, such as an appointed liaison, designated health department staff onsite at the jail, regular staff and management meetings, or written agreements. Discharge planning was rated as the least effective area of collaboration. None of the 20 jails had developed an organized system for LTBI discharge planning; only 13% of TB cases in the study completed treatment in jail. Most jails provided TB patients with contact information for the health department, but only 50% made appointments with the health department for the released inmate to continue treatment. Only one of the 20 jails in the study used incentives.

CDC made several recommendations to jails based on the evaluation study results. More comprehensive screening and diagnostic evaluations should be provided. Policies and practices to screen high-risk inmates with chest x-rays should be strengthened. Isolation procedures, ventilation systems and other environmental controls should be enhanced. TB contact investigation protocols should be developed or strengthened. CDC also identified items that should be included in an action agenda. The increased effectiveness of TB programs that actively and regularly collaborate with local jail systems should be widely communicated. Data should be compiled and disseminated to demonstrate the need to improve TB screening and discharge planning in jails.

CDC's 1996 correctional guidelines should be evaluated to determine the appropriateness of the recommendations in the context of current TB knowledge. CDC will convene a workgroup of correctional and public health experts in October 2003 to address this issue. Consideration should be given to sponsoring demonstration projects on best practices in correctional settings. CDC should explore the possibility of providing jails and health departments with TB contract language to be used in negotiations with private vendors of inmate health care.

ACET made several suggestions about the current state of TB prevention and control in jails. CDC should conduct demonstration projects with jails to identify barriers to utilizing available resources. Jails are not using the jail infection control template or other existing tools to create standard methods, protocols and policies for TB control and prevention. Jails that have created strong collaborative relationships with HRSA-funded community health centers (CHCs) should be included in the demonstration projects. Many homeless persons who are released from jail present to CHCs for follow-up TB care and treatment.

Local health departments should share TB screening data with homeless shelters and transient hotels. CDC should develop language for jail health care contracts because many private vendors charge inmates a fee to seek health care. ACET acknowledged that TB control and prevention in correctional settings is another area adversely impacted by the inadequate TB budget. Health departments are struggling to adhere to CDC's 1996 guidelines to collaborate with jails because nurse coordinators, outreach workers and other key staff are being cut from TB programs.

CDC announced that the U.S. Surgeon General initiated a call to action on correctional health. This initiative can serve as a platform to obtain Congressional support and additional funding for the issue. As the lead agency for this activity, CDC has already briefed the U.S. Surgeon General and is now establishing workgroups. DTBE will seek input from ACET on mechanisms to highlight TB in correctional settings and surrounding communities as the call to action document is being developed.

### Update on the CDC/Bureau of Immigration and Customs Enforcement (ICE) Collaboration

Dr. Diana Schneider is the ACET *ex officio* for the Division of Immigration Health Services (DIHS). She explained that the mission of DIHS is to protect America by providing health care and public health services in support of immigration law enforcement. The mission of Detention and Removal Operations (DRO) is to promote public safety and national security by ensuring the departure of all removable aliens from the United States through fair and effective enforcement of the nation's immigration laws. DIHS is extremely pleased that DRO recently assigned a staff member to exclusively focus on health issues.

DIHS provides initial screening for mental and physical health conditions of detainees, including TB screening. Approximately 5,000 immigration detainees are held in facilities directly staffed with DIHS health care providers on a daily basis; 15,000 detainees are held in contract facilities or local and county jails. Of all DIHS facilities, seven or eight have tele-radiology capacity to screen for active TB with chest x-rays. The remaining facilities perform conventional screening with TST followed by chest x-rays for positive results. DIHS uses a covered benefits package to assess and treat detainees for chronic diseases, HIV/AIDS, diabetes, hypertension, mental illness and other conditions while in custody. Efforts are made to keep detainees in the United States if the home country does not provide medical services for serious health conditions.

DIHS provides pharmacy services, medical escorts, epidemiology and infectious disease surveillance, and onsite primary health care at 12 facilities, managed care at

offsite or short-stay units, negative pressure isolation at six facilities, and long-term care for detainees requiring prolonged hospital stays. For immigration detainees with TB, DIHS has been responding to ACET's recommendation to establish an interagency policy group with representatives from HHS, the Department of Justice (DOJ) and other key organizations. The goal of the workgroup is to reach consensus on mechanisms to continue TB therapy for Immigration and Naturalization Services (INS) detainees after detention. After ACET's recommendation was made, functions of the former INS were transferred from DOJ to the Department of Homeland Security (DHS).

The interagency workgroup was established in November 2002 and has convened five face-to-face meetings or conference calls to date. Workgroup members are represented by CDC, DIHS, ICE and state and local health departments. The workgroup has taken several actions in response to ACET's recommendation. First, an ICE directive was drafted and if approved, the DRO Director will distribute a memorandum requesting that field office directors consult with DIHS prior to transferring, releasing or removing detainees. To support the directive, DIHS has implemented TB surveillance in its facilities and contract jails that hold immigration detainees.

DIHS will notify ICE after a TB case has been identified in a facility and request that the detainee be held until all appropriate referrals and notifications are made. ICE will have final decision-making authority, but must provide justification if its decision differs from DIHS's recommendation. The next step in this process will be for the workgroup to establish a subgroup to thoroughly assess federal immigration authority versus state quarantine laws and policies. Second, a protocol was established for DIHS facilities and contact jails to request TB case information for detainees. Language was drafted for ICE detention standards that addresses the need for contract facilities and local jails to consult with DIHS prior to transferring, releasing or removing detainees with active TB. DIHS detention standards also address TB screening at intake, TB infection control and notification. If the ICE directive is approved, facilities will consult with DIHS before transferring, releasing or removing immigration detainees; allow DIHS to make appropriate referrals to health departments and other TB control organizations; and coordinate removals for detainees with TB returning to Mexico.

DIHS is making efforts to model the directive after the Arizona "Meet and Greet" Program and implement the activity on a national level. ICE will have final decision-making authority in recommending medical holds. DIHS is currently requiring field staff to use a standard operating procedure to report, refer and register TB cases with CURE-TB or TB Net as appropriate and notify National TB Control Departments in the home countries of immigration detainees. Because field staff are feeling burdened with duplicate reporting mechanisms, DIHS welcomes input from ACET in addressing this concern.

Both ACET and CDC acknowledged the diligent efforts of DIHS and DTBE staff in responding to ACET's recommendations to establish the interagency policy workgroup and devise mechanisms to address immigration detainees with TB. These activities will undoubtedly result in critical public health actions. The need for DIHS and ICE to closely collaborate with the U.S./Mexico Border Health Commission in developing agreements to return TB cases to Mexico was noted.

### CDC Activities for Foreign-Born TB

<u>U.S./Mexico</u> <u>Binational</u> <u>TB</u> <u>Referral</u> <u>and</u> <u>Case</u> <u>Management</u> <u>Project</u>. Dr. Eileen Schneider of DTBE described the progress made on this activity since the previous ACET meeting. Based on 2001 data of pulmonary TB incidence, the Border rate of 6.9/100,000 was higher than the national rate of 4.5/100,000 in the United States. The Border rate of 28.1/100,000 was higher than the national rate of 16.2/100,000 in Mexico. Mexican-born TB patients were twice as likely as U.S.-born TB patients to move or become lost to follow-up. The U.S./Mexico binational TB referral and case management project was developed to ensure continuity of care and completion of therapy for TB patients who migrate between Mexico and the United States.

The project is also designed to reduce TB incidence and prevent drug resistance in both countries; coordinate referral of patients between health systems; and provide a model for other diseases. The referral/counter-referral system is based on CDC binational TB projects, the San Diego County Health Department CURE-TB, and the Migrant Clinicians Network TB Net. The project was launched on March 27, 2003 and created with a bilingual binational health card that contains a unique identification number to track patients, location where the card was issued, treatment initiation date, date of last TB treatment dose, treatment regimen, DOT or non-DOT administration of treatment, and toll-free telephone numbers in Mexico and the United States.

The unique identification number replaces the patient's name, does not reference TB, and links the card, patient and clinical data to two national databases. The toll-free telephone numbers can be used by providers to obtain additional clinical data or by patients to locate an appropriate facility to receive care. Both Mexico and U.S. patients with active TB can be enrolled in the project, but U.S. patients are also eligible by being born in or bound for Mexico regardless of place of birth. These factors include recent arrival to the United States from Mexico; migrant worker; immediate family in Mexico; U.S. employment/Mexico resident; or U.S. resident/medical care in Mexico. The binational TB card project is designed as follows.

TB providers register eligible patients in complimentary databases in Mexico or the United States, educate patients, and issue a binational health card. Databases maintain essential data elements about the TB treatment of patients and are updated every two to four weeks. When a patient moves or anticipates a move across the Border, the TB provider will notify the receiving referral system in Mexico or the United States and issue a two-week supply of TB medication to the patient if possible. The sending referral system provides the receiving referral system with the patient's TB treatment and destination information. The receiving referral system notifies the local TB control program or provider in the destination location, registers the patient's binational health card information in the database, and reports final outcomes to both Mexico and the United States.

The project is being piloted in four companion U.S./Mexico Border regions, three ICE detention centers in the United States, and six interior Mexican states. Chicago and Tennessee will be added as pilot sites. The binational TB card project has already improved communication and collaboration between ICE detention centers and local TB programs. As of September 18, 2003, two U.S. sites distributed 114 binational health cards and referred 14 patients who moved to Mexico during TB treatment; three Mexico sites distributed 235 binational health cards and referred three patients who moved to the United States during TB treatment. The project is supported by \$510,000 from CDC and two other U.S. sources and \$180,000 from two Mexico sources.

A protocol was developed to evaluate the efficiency and cost of the project; the ability of the project to facilitate completion of therapy for TB patients traveling across the U.S./Mexico Border; and the feasibility of replicating the project in other sites or for other diseases. In May and July 2003, site visits were conducted to informally evaluate the project in Texas, California and the Mexican National TB Program. In November and December 2003, site visits will be conducted to formally evaluate the project at U.S. and Mexican Border sites. All partners will attend a meeting in January 2004 in Mexico City to discuss the progress and performance of the project and address problems.

CDC and the Mexican National TB Program are leading the project, but several U.S. and Mexican agencies at federal, state and local levels as well as NGOs with a focus on binational and U.S./Mexico Border health issues are also actively engaged. The project is responding to identified TB needs in the region; representing a consensus for binational collaboration; improving treatment outcomes; and providing a model for other sites or diseases. If the pilot sites demonstrate success, CDC plans to broaden the project to other areas in the United States and Mexico.

<u>Electronic Disease Notification (EDN) System.</u> Mr. Subroto Banerji of DTBE reported that the first release of DGMQ's EDN system will focus on TB. EDN-TB is designed to address many inherent challenges of the current paper-based TB notification system.

At the local level, EDN-TB will serve as a web-based information system to be accessed by local or state health departments through a secure data network server. In accordance with HHS regulations for newly built systems, EDN-TB will undergo a rigorous security evaluation. Web-based technologies will be used to strengthen health department capacity to identify and evaluate immigrants or refugees with TB on a more timely basis.

Program analysis and evaluation will be supported at local, state, national and overseas levels. Overseas medical reports will be electronically captured and portable document files of these forms will be created. State and local health departments will be alerted about new arrivals by e-mail notification each night. The movement of any individual whose destination differs from the overseas forms will be tracked. Health departments will be able to enter U.S. evaluation data online, produce electronic versions of reports and download jurisdictional data for local analysis.

At the CDC level, EDN-TB will allow overseas and U.S. medical evaluations to be compared. CDC's role in systematically conducting quality control assessments of overseas panel physicians will be strengthened over time. A nationwide analysis of these data will be supported to inform future programmatic decisions or changes in technical instructions. Data on migrating populations resettling in the United States will be collected in the future. CDC has scheduled September 2004 as the national roll-out date for EDN-TB. Specific activities will be conducted from October 2003-August 2004 to prepare for this event, including security application, beta testing, programming, and web-based national training of state and local TB coordinators.

The EDN-TB external workgroup will assist CDC in revising and finalizing the worksheet, report specifications, performance indicators and user's manual. CDC is considering the external workgroup's recommendation to modify the current worksheet to capture culture data from U.S. evaluations. The external workgroup is represented by California, Florida, Illinois, Georgia, Massachusetts, New York City, New York State, Texas and Virginia. These jurisdictions account for nearly 70% of all TB notifications generated.

Revised Technical Instructions for Civil Surgeons. Dr. Mary Naughton of DGMQ reported that the major changes to the TB component of the 1991 technical instructions focus on TST, chest x-rays and revised classifications. The 2003 technical instructions now offer more explicit guidance to civil surgeons who administer medical examinations to persons applying for legal permanent residence in the United States. TST is required for all applicants two or more years of age regardless of pregnancy or prior BCG vaccination. Exceptions to this requirement are a history of blistering with prior TST or documentation signed by a health care provider of a prior TST reaction ≥5 mm. A chest x-ray is required in both circumstances.

A chest x-ray is also required for pregnant applicants with a TST reaction ≥5 mm. Asymptomatic pregnant women are no longer excluded from this requirement. The applicant can decide whether the chest x-ray should be performed during or after pregnancy, but the civil surgeon should explain that the risk to the fetus from radiation is low. The chest x-ray must be performed and interpreted; any treatment for infectious TB must be completed before medical clearance is granted. For applicants with TST reaction <5 mm, a chest x-ray is required if the patient has signs or symptoms of active TB disease or is immunosuppressed for any reason, including HIV infection, a history of organ transplant, or a current treatment regimen of ≥15 mg of prednisone per day for one month or longer.

The 2003 technical instructions contain an appended glossary of chest x-ray findings that is essentially the same as provided to panel physicians. The findings are categorized by "active TB disease" and "inactive TB disease." The glossary also includes TB findings not requiring follow-up. The new Class B category for "LTBI needing evaluation for treatment" has been added to address recent arrivals to the United States within the past five years; persons from countries with high TB prevalence; persons with a TST reaction ≥10 mm; and persons with no evidence of active TB disease. For certain conditions, evaluation for LTBI treatment is recommended when TST is 5-9 mm. Civil surgeons are strongly advised to contact the TB program at the local health department to identify specific sources of LTBI treatment and make appropriate referral.

Class B3 is eliminated from the 2003 technical instructions because no significant association was seen with active TB. This classification addressed discrete calcified nodule or calcified lymph node. The TST instructions have been expanded to focus on storage of PPD, administration and interpretation. The TB core curriculum developed by DTBE in 2000 served as the basis for expanded TST instructions and is included in Appendix A. Stronger emphasis is placed on the need for civil surgeons to refer patients to the health department if abnormal chest x-rays suggest TB. The health department will be responsible for further evaluation of the patient with sputum smears, cultures or drug susceptibility testing as needed. Medical management, treatment and contact investigations will also be under the purview of health departments.

An algorithm is included in the 2003 technical instructions illustrating the process by which civil surgeons should refer patients to the health department. The graph clearly suggests that patients with signs or symptoms of TB, regardless of TST or chest x-ray findings, should be referred to the health department for further evaluation. The I-693 Form is now under the authority and control of the Bureau of Citizenship and Immigration Services (BCIS) in DHS. Civil surgeons use the form to document the patient's health condition and grant medical clearance. The revised I-693 Form was

recently submitted to the BCIS Form Approval Department and is expected to be printed and distributed by the end of CY'03.

Paper copies of the 2003 technical instructions will be disseminated to ~3,000 civil surgeons along with a cover letter listing the major changes. The DGMQ web site will contain the technical instructions, frequently asked questions and updates as needed. At this point, the technical instructions have been cleared by both the DGMQ and DTBE Associate Directors for Science. Other DTBE senior staff must review the technical instructions and submit comments no later than October 8, 2003.

TB in Foreign-Born Persons in the United States and Canada. Ms. Dolly Katz of DTBE described a prospective population-based study that will be conducted to address this issue. In 2002, TB cases among foreign-born persons accounted for 51% of cases in the United States. The gap in TB rates between foreign-born and U.S.-born persons has been widening over time. In 1992, the TB rate was 34.5/100,000 among foreign-born persons versus 8.2/100,000 among U.S.-born persons. The rates changed in 2000 to 23.6/100,000 among foreign-born persons versus 2.8/100,000 in U.S.-born persons. Mexico alone accounts for ~25% of TB cases in foreign-born persons; China, India, the Philippines and Vietnam contribute >30% of the burden.

Data show that in the United States, foreign-born persons are developing TB at a rate of >8 times higher than U.S.-born persons. To address missed opportunities in preventing TB in foreign-born persons, CDC will conduct a prospective population-based study of the epidemiology of TB in foreign-born persons. The study will be implemented by 22 TBESC sites at academic, research and public health institutions in 16 states and two Canadian provinces. The sample will include 1,500 newly-diagnosed patients. All cases will be recruited at smaller sites, while a 20% random sample of adult cases, all pediatric cases <5 years of age, and all source cases identified by a health department will be enrolled at larger sites. The 12-month enrollment period is scheduled to begin in June 2004.

With a budget of \$2.6 million, CDC will conduct three major activities. First, in-depth and face-to-face interviews will be conducted with study participants. The one-hour questionnaire will focus on immigration, visa status and history; sociodemographic factors; symptoms prior to TB diagnosis; use of home remedies, non-traditional providers and other care-seeking behaviors; amount of time between the onset of symptoms and first physician contact or TB diagnosis; and history of TB testing and LTBI treatment. Sociodemographic factors will include residence in or visits to specific countries or refugee camps, income, occupation and education. The questionnaire will be translated into seven major languages. All interviewers will be required to undergo cultural sensitivity training.

Second, state case numbers will be used to link the names of study participants to DGMQ databases that contain TB screening data on immigrants and refugees. The DGMQ databases will provide the study with the patient's TB screening test results upon U.S. entry, arrival date, port of entry, destination, visa status and TB class. The files will also inform the study whether the patient's data were reported to the local jurisdiction and if the local jurisdiction made a follow-up report to DGMQ. Third, surveillance data and clinical information routinely gathered in the United States and Canada will be abstracted from TB report forms. These files will provide the study with the site of the disease, initial drug regimen, and results of skin tests, chest x-rays, smears, cultures and drug susceptibility testing.

To date, CDC has awarded contracts to all 22 TBESC sites and established collaborations with both internal and external partners. The study protocol and adult questionnaire were submitted to the CDC Institutional Review Board (IRB); the pediatric questionnaire is being refined; and a protocol manual is being developed. Confidentiality certificates were requested for all 22 sites to protect study data against subpoena. The CDC Office of General Counsel is conferring with immigration authorities to determine whether the confidentiality certificates will protect illegal aliens in a research project. All grantees are developing site-specific sampling plans and contacting local IRBs. Two subcommittees are developing a comprehensive training session for interviewers and designing a protocol to pilot the questionnaire, enter data and select study participants. For example, immigrants or refugees incarcerated for the entire study period will not be eligible to participate.

ACET weighed in on CDC's activities for foreign-born TB. CDC is to be commended on the initial success of the innovative binational TB card project, but several issues should be considered. New resources may need to be leveraged and creative mechanisms may need to be developed to care for and manage additional TB patients identified by the project. Caution must be taken to avoid reflecting binational TB cases in morbidity rates of U.S. states. Prisons should be considered as the next setting to replicate the project due to inadequate communication and collaboration in correctional health.

ACET urged CDC to take action on the external workgroup's recommendation. The EDN-TB worksheet should be revised to capture culture data from U.S. evaluations. Because smears only identify 40%-50% of culture-positive cases, a large proportion of immigrants and refugees enter the United States with culture-positive active TB. CDC should consider the Canadian approach in which cultures rather than smears are used for TB screening. ACET extensively discussed the 2003 technical instructions for civil surgeons. CDC should consider using Class A for "clinically diagnosed active TB" or "culture-positive active TB." U.S. civil surgeons should not use the same classifications as overseas civil surgeons because cultures are not performed abroad. Most notably,

the B1 classification for patients with culture-positive smear-negative TB is inappropriate for U.S. civil surgeons.

ACET was deeply concerned about CDC's lack of oversight in assessing the performance of civil surgeons in implementing the technical instructions. Incorporating the QFT-TB test into the skin testing process should be explored in this effort. ACET noted that the immunosuppression revision should be refined to clarify "history of organ transplant." For example, the 2003 technical instructions should explicitly include or exclude a patient with a failed renal transplant who had the organ removed and is no longer on immunosuppressive therapy, but is on dialysis.

CDC made follow-up remarks to ACET's comments. Technical instructions for panel physicians are currently being evaluated to assess whether the algorithm should be changed to include cultures. If the activity is determined to be feasible, CDC will first undertake this effort with Mexico. In the interim, however, CDC is currently analyzing a new diagnostic to improve smear sensitivity. Recent study results showed an improvement rate of 30% in smears alone. CDC is requesting that ACET consider several disadvantages to including a section on the QFT-TB test in the 2003 technical instructions.

Current knowledge and experience may be insufficient since the QFT-TB test has not been extensively used in foreign-born populations. Civil surgeons are not TB specialists and lack necessary skills to use the QFT-TB test for screening. Production and dissemination of the I-693 Form would be delayed; the cost of using the QFT-TB test would need to be evaluated as well. In terms of the modified classifications, CDC clarified that applicants are evaluated and treated based on culture. The civil surgeon cannot clear the applicant until treatment is completed. With respect to performance assessments, CDC agreed that progress in developing a domestic quality assurance program for civil surgeons has been minimal. ACET's endorsement of this activity would strengthen CDC's justification to BCIS about the need to design a civil surgeons certification program.

ACET and CDC agreed that the following actions should be taken before the 2003 technical instructions for civil surgeons are finalized and distributed. CDC will note in the technical instructions that the QFT-TB test is not yet available, but FDA approved the test and CDC issued guidelines. CDC will disseminate additional information when the QFT-TB test becomes available, particularly its recent data on use of the test in Vietnam and new antigens to identify active TB. CDC will review and refine the technical instructions to address ACET's concerns about the revised classifications and organ transplant history. If a civil surgeon training and certification program is developed, DGMQ should have authority in overseeing this process.

### Local and State Activities for Foreign-Born TB

<u>San Francisco</u>. Dr. Kawamura is the TB Control Program Director for the San Francisco Department of Public Health (SFDPH). She described activities SFDPH conducted to evaluate its progress in implementing guidelines for TB control among foreign-born persons. Of San Francisco's population of ~765,000, 37% is foreign-born. Most foreign-born persons in the city are Asians who are geographically concentrated in Chinatown and have a 50% LTBI prevalence among adults. In 1990-2002, Asians accounted for the highest TB case rates in San Francisco.

The 146 new TB cases reported in 2002 reflected a record low in the city, but the case rate of 18.4/100,000 is still three times the U.S. rate of 5.8/100,000. Of San Francisco's TB cases in 1997-2002, 75% were foreign-born with 37% of these persons in the United States for less than five years and 18% in the country for less than one year. The importation of MDR-TB is another issue of major concern for SFDPH. INH resistance has been relatively stable for the past 20 years at ~10%, but eight MDR-TB cases were detected in seven Asians and one Mexican from 2001-2002.

SFDPH identifies active TB cases through contact investigations and the immigrant B notification follow-up program. Targeted testing is accomplished by a clinic network that tests and screens with TST and refers TST-positive patients to the SFDPH TB control program. A TB screening and prevention site in Chinatown is also used for targeted testing. SFDPH reviewed its TB control surveillance data from 1997-2002 to evaluate the percentage of all foreign-born TB cases each activity generated. Contact investigations, B notification, targeted testing of foreign-born persons, targeted testing of new arrivals <1 year in the United States, and passive case finding yielded 3.6%-46% of cases. The case detection rate for these activities in the same time period ranged from 1% for contact investigations to 6% for B notification.

In San Francisco, foreign-born persons who are health care workers, patients of some community clinics, or school students, employees or volunteers are required to be screened for TB. While local pediatricians adhere to the American Academy of Pediatrics (AAP) guidelines and screen for TB, local primary care providers (PCPs) generally do not comply with SFDPH or CDC guidelines. PCPs typically do not view TB as a primary care issue for foreign-born persons. Local practices prompted SFDPH to compile 1997-2002 data and generate preliminary results for targeted testing and TB screening of foreign-born persons. Of ~13,500 foreign-born persons referred for evaluation, 81% were assessed. Of the evaluated group, 61% were arrivals <5 years in the United States; LTBI was detected in 95%; and the LTBI completion rate was 72%.

SFDPH reviewed 1999-2001 data on legal immigration status to assess the decline in TB cases and case rates among foreign-born persons. Using a numerator of new

arrivals <1 year in the United States infected with TB, ~50% of the cohort was screened. SFDPH realized that this approach was limited because the numerator also includes undocumented immigrants, students and persons with non-permanent visas. As a result, the percentage of infected new immigrants screened by SFDPH represents a crude overestimation. In addition to its internal assessment, SFDPH also evaluated the strengths and limitations of the Foreign-Born TB Workgroup recommendations. The guidelines were published in the September 18, 1998 issue of the *MMWR Reports and Recommendations* (*R&R*).

In general, SFDPH found the guidelines to be relevant and excellent for both CDC and health departments. However, the workgroup recommendations do not constitute official ACET or CDC guidance that can be directed to TB control programs. The guidelines are not well known or widely utilized and are almost exclusively targeted to the documented foreign-born population or persons seeking to adjust their legal status. In particular, SFDPH identified several key elements missing from the guidelines. For local epidemiologic profiles, CDC rather than health departments should develop B notification variables to ensure that methods are standardized. Health departments should be advised to collect visa information as part of routine surveillance or for research purposes. CDC should review data collected by civil surgeons and provide oversight of civil surgeons.

Local programs cannot provide feedback to civil surgeons or determine whether a population should be targeted because information gathered by ICE is not examined. Many undocumented immigrants and new arrivals are screened through the adjustment process. For case finding, screening and preventive treatment, LTBI screening should be performed overseas and across the U.S./Mexico Border for all immigrants prior to U.S. entry. Domestic or local TB screening of new arrivals is highly inefficient and dependent on programs and other health care resources. Follow-up of foreign-born persons with a positive TB status is more logical than efforts to identify all new arrivals. The second-generation QFT-TB test should be included in the routine blood panel to distinguish between BCG and true TB infection.

Students, workers and all other foreign-born persons with long-term non-permanent visas should be screened for TB overseas. Screening should be required for individuals seeking asylum. CDC and health departments should implement strategies that highlight LTBI as an important primary care issue for new arrivals and foreign-born persons, particularly if diabetes, renal failure or other medical risk factors for TB are present. Cost-effective studies should be conducted to determine whether foreign-born persons <35 years of age who are infected with TB should be targeted for treatment. CDC should develop indicators and national performance standards for B notification. Screening strategies for undocumented persons should be addressed.

CDC should collaborate with HRSA and other federal agencies that provide primary care to foreign-born populations to standardize routine TB screening as a program requirement. For diagnosis and management, sputum culture and susceptibility testing should be required for all smear-positive immigrants who started TB treatment overseas prior to U.S. entry. Domestic work-up is often invalidated by treatment since immigrant TB cases often arrive in the United States with partial or inadequate regimens. CDC should establish a formal reporting/feedback system to panel physicians, particularly for quality assurance of missed smear-positive cases. International notification and case management facilitation should be expanded to Hong Kong, the Philippines and other countries with high rates of returning immigrants. The CURE-TB model in Mexico should be used to replicate this activity. A solid process should be developed to diagnose undocumented individuals.

For <u>training needs</u>, local health departments do not have sufficient expertise, dedicated health educators and other tools to conduct training needs assessment. SFDPH did not identify any key elements missing from the recommendation to <u>collaborate with CBOs</u>. Based on its evaluation of both internal activities and the 1998 foreign-born TB guidelines, SFDPH concluded as follows. Local programs need efficient strategies to locate active and latent TB in foreign-born persons as well as program indicators to assess effectiveness. Improved B notification follow-up, LTBI diagnosis prior to U.S. entry, and overseas laboratory capacity for culture and susceptibility testing will have the greatest impact on local programs and low-incidence areas. Separate strategies should be developed to address undocumented individuals.

Arizona. Ms. Elizabeth Williams is the TB Surveillance Coordinator for the Arizona Department of Health Services (ADHS). She described activities ADHS is conducting to address persons with TB who are deported prior to completion of therapy. From 1997-1999, 17 cases of active TB were diagnosed among ICE detainees, but none completed therapy while in custody for an average of 56 days. Of the 15 deported cases, three completed treatment in either the United States or Mexico and 12 have unknown outcomes. The remaining two cases were transferred out of state and also have unknown outcomes. The percentage of TB cases diagnosed in correctional facilities slightly decreased in the United States from 1993-2003, but Arizona's percentage of 7.3% was the highest in the country in 2002.

Based on preliminary 2003 data, >14% of all cases in the state have been diagnosed in correctional facilities. ICE detainees account for 60%-70% of Arizona's total TB cases in correctional facilities. To address this issue, ADHS developed a two-pronged approach to prepare detainees with TB for deportation. The first activity was initiated by a meeting in November 2000 in an Arizona county with a large number of prisons. ADHS staff, correctional officials, county health department staff and medical staff from the county correctional facilities were in attendance. The deliberations resulted in

CURE-TB being selected for Arizona's U.S./Mexico binational referrals. The card given to CURE-TB enrollees has toll-free telephone numbers in both the United States and Mexico that can be called to locate the nearest facility for free TB treatment.

Other features of the program include a repository of patient medical records for treating physicians and outcome data for referring health departments. Patients are allowed to speak with CURE-TB staff prior to deportation, but these discussions are not possible at all facilities due to differences in institutional policies and procedures. ICE is closely collaborating with ADHS on the CURE-TB referral program. All TB suspects and cases from Mexico detained in the ICE facility in Florence, Arizona are enrolled in CURE-TB. The physician completes the CURE-TB referral form during the first patient visit immediately following an abnormal chest x-ray reading.

As of June 30, 2003, 60 TB suspects and 12 confirmed TB cases were identified at the ICE-Florence facility. The ability to identify TB suspects was expedited when ICE initiated radiology capacity in 2001. Of all TB cases at the facility, 50% were from Mexico. ADHS views CURE-TB as a safety net for deportees who are unwilling to stay in Mexico to complete treatment. ADHS's second activity was triggered by an MDR-TB case scheduled for deportation to Mexico in December 2001 and led to the development of a new protocol. The "Meet and Greet" (M&G) program is partially supported by TB cooperative agreement funds and uses special housing in Nogales, Sonora for deported TB patients.

M&G is a state-to-state agreement between Arizona and Sonora that arranges for Mexican nationals to be met at the U.S./Mexico Border and offered TB treatment. Correctional facility health providers notify ADHS when TB is suspected in persons who may be subject to deportation. ADHS notifies local ICE officials that the detainee will need special arrangements for deportation due to medical reasons. ADHS, ICE and correctional staff periodically communicate to anticipate the deportation date. ICE officials agree to hold the detainee until the next business day when the deportation is ordered. M&G is an extremely important program due to the desire of Mexican health officials to treat TB cases among Mexican nationals.

Based on preliminary 2002 data, 12 deportees had a mean length of treatment while in custody for 52 days. Of five deportees referred to both M&G and CURE-TB, one completed treatment, one is still undergoing therapy in Mexico and three are lost. Of three deportees referred to CURE-TB only, one completed treatment and two are lost. Of four deportees referred to TB Net, one continued treatment for four months after returning to Central America and became lost and three have unknown outcomes. For Mexican deportees only, 38% were likely to complete therapy in 2002. This figure is significantly higher than Arizona's 17% completion rate in 1997-1999.

Based on preliminary 2003 data, 18 ICE detainees diagnosed with TB to date reflect 11 cases from Mexico, four from Central America and three from Asia. These persons have either been deported or are awaiting deportation. ADHS has been informed that all ICE detainees in Arizona will now be deported though Texas to reduce deaths associated with U.S./Mexico Border crossings and to decrease returns to Arizona. The new policy may have implications for both ADHS referral programs. One of the most significant activities in the future will be to enroll the entire state of Arizona in the U.S/Mexico binational TB card project. ADHS anticipates that ~50% of total TB cases in the state will be eligible. ADHS will develop a card with telephone numbers for Arizona and Mexican clinics for distribution in Nogales, Sonora. The clinic reported that three of four recent arrivals planned to return to Arizona after leaving.

ACET Discussion and Recommendations. The floor was opened for ACET to propose additional next steps and recommendations to address TB prevention and control in correctional settings and foreign-born populations. Agreement was reached to add these two issues to Dr. Kawamura's letter to the HHS Secretary that will outline adverse impacts the inadequate TB budget is having on TB elimination strategies. The letter will specifically point out that neither new immigrants nor local health departments should be burdened with the cost of TB or LTBI treatment. The requirement for foreign-born persons was made at the national level and should be supported by federal agencies.

A suggestion was made for CDC to release a blanket statement to address foreign-born TB and explicitly point out that BCG does not count. ACET did not reach agreement to formalize this suggestion because the issue will be moot after the second-generation QFT-TB test is available. Several suggestions were made to address the reluctance of PCPs to comply with TB screening guidelines for foreign-born persons. TB controllers can make presentations at national and local meetings of HRSA-funded CHCs as well as events sponsored by AAP and similar professional organizations. Outreach efforts can be targeted to students in the medical field and other allied health professions. Linkages with the National Institutes of Health's upcoming project to fund 31 medical schools and train students in TB issues should be explored in this effort.

CDC was reluctant to act on the IOM recommendation to perform LTBI screening overseas at this time. Health departments must first improve follow-up of foreign-born persons with active TB. To identify local practices for foreign-born TB, CDC expressed a strong interest in learning whether health departments other than SFDPH also evaluated the 1998 foreign-born TB guidelines. Members of the National Tuberculosis Controllers Association (NTCA) could be polled to provide CDC with this input. ACET formed a workgroup to follow up on CDC's request. Drs. Escobedo, Fleenor, Naughton, Reves, Reichman, Solorzano and Ms. Loaiza will serve as workgroup members; two DTBE staff members and a HRSA representative will be designated as well.

Dr. Kawamura charged the new ACET Foreign-Born TB Workgroup as follows. The workgroup will review the 1998 guidelines, collect existing data on foreign-born TB, and identify key elements missing from the guidelines. The workgroup will focus on foreign-born persons legally entering the United States and will not address undocumented individuals. The workgroup will formulate recommendations on foreign-born TB and present these items to ACET for review, comment and formal approval. The workgroup will ensure that its foreign-born TB recommendations are consistent with the TB control statement currently being revised by the ATS/CDC/Infectious Disease Society of America (IDSA) workgroup.

There being no further business or discussion, Dr. Kawamura recessed the ACET meeting at 4:57 p.m. on October 1, 2003.

### **ACET Business**

Dr. Kawamura reconvened the ACET meeting at 8:39 a.m. on October 2, 2003 and entertained a motion to accept the previous meeting minutes. The motion was properly made and seconded by voting members. There being no changes or further discussion, the June 4-5, 2003 ACET Meeting Minutes were unanimously approved. Dr. Kawamura announced that several agenda items suggested at the previous meeting were addressed. She led ACET in a review of other agenda items to add to the remaining topics.

- Report by the Correctional Health Workgroup on its progress in revising CDC's 1996 TB prevention and control guidelines in correctional settings.
- Presentation by Dr. Charles Nolan on the TB control statement being revised by the ATS/CDC/IDSA workgroup.
- Overview of TB prevention and control in the private sector, including outreach efforts to organized medicine.
- Presentation on foreign-born TB screening practices of PCPs in HRSAfunded CHCs.
- Update by DTBE and GAP on CDC's global TB prevention and control activities.
- Status report on TB research.
- Overview of homelessness, substance abuse and other TB risk factors.
- Status report on CDC's TB budget in general and allocations to specific TB activities in particular.
- Presentation on the strategic plan for TB training and education in relation to CDC's public health standards; core competencies for TB nurses; and strategies by CDC, the Association of State and Territorial Health Officials,

and the National Association of County and City Health Officials for TB workforce and leadership development.

ACET added other topics to the existing agenda item on new TB diagnostics, tools, vaccine and drug development: Phase I/Phase II trials of the TB Vaccine Blueprint, a new TB vaccine being tested in Europe clinics, TB vaccines to be tested in the United States within the next year, and QFT-TB test trials.

### **Update on Targeted Testing**

Dr. Zachary Taylor, the FSEB Chief, described DTBE's targeted testing projects. The new five-year cycle for cooperative agreements to state and local partners began in FY'00 with funding of \$5.8 million. Awards ranging from \$23,000 to \$1.9 million were made to 12 state and five local programs to develop targeted testing projects. Of the grantees, nine programs in low- to medium-morbidity areas received <\$150,000 and eight programs in high-morbidity areas received >\$150,000. Morbidity areas are defined in comparison to national average TB case rates. The 83 different interventions developed by the 17 grantees target foreign-born populations, correctional facility inmates, homeless individuals, HIV-positive persons, residential and outpatient drug treatment programs, children <5 years of age, African Americans, recent TB converters and transgenders.

Some grantees supplemented existing testing and treatment programs, while others developed entirely new interventions. New projects were typically associated with longer startup times and more challenges due to the need to identify a target population, conduct outreach activities, establish the targeted testing intervention, and screen and treat persons detected with LTBI. A range of services are provided by the 83 interventions, including TST, referral and treatment, directly observed preventive therapy for high-risk patients, community outreach and education, case management of social barriers to treatment acceptance and completion, incentives or enablers, and expanded clinic hours or other structural enhancements. Eight interventions in six project areas were discontinued due to low LTBI rates, a shift in focus of partner organizations, and issues related to hiring and maintaining staff.

Other challenges the grantees encountered included budget cuts; low rates of treatment acceptance and completion; difficulty in accessing homeless persons, correctional facility inmates and other target populations; resistance among providers in administering LTBI treatment; and flawed designs of data management systems. Several problems are hindering DTBE's ability to evaluate and compare outcomes of the targeted testing projects. Mechanisms to report results are inconsistent among grantees, particularly since use of the aggregate report of program effectiveness form

was suspended due to lack of approval from the Office of Management and Budget. Identifying outcomes specifically related to targeted testing funding is difficult for projects that supplemented existing programs.

At this point, outcome data on the targeted testing projects are not complete. Some project areas have still not submitted progress reports to DTBE demonstrating that any individual in the target population completed treatment. Delays are often due to the grantee conducting research, outreach and other background activities to establish the intervention. After the program is initiated, the grantee must then evaluate the intervention, begin treatment of the target population and ensure treatment completion. However, grantees with existing testing and treatment programs and established data management and collection systems generally reported better outcomes than new projects.

Based on these results, 58%-91% of a target population are evaluated, 18%-95% initiate treatment, and 16%-91% complete treatment. CHSRB will soon conduct a formal evaluation of the targeted testing projects to assess best practices of the interventions and compliment and expand the grantees' self-evaluation efforts. The formal assessment will be based on CDC's six-step evaluation framework. DTBE plans to use the evaluation findings and lessons learned to enhance existing and future interventions. When the cooperative agreement is re-competed in FY'05, current grantees, programs with true targeted testing interventions and projects with demonstrated effectiveness will be eligible for funding.

Only ~\$1 million will be available for targeted testing projects in the new program announcement; the remaining \$4.8 million will be redirected to training other DTBE project sites and establishing additional Model TB Centers. The significant budget cut will prevent DTBE from funding the best interventions, identifying lessons learned, and applying best practices to increase the effectiveness of targeted testing in other areas.

ACET extensively discussed the complexities of targeted testing. Most notably, targeted testing is a low priority in the TB arena and receives inadequate funding from federal agencies and minimal attention from health departments. ACET made several suggestions to enhance targeted testing. During the formal project evaluation, CDC should also obtain lessons learned from the discontinued interventions. TB controllers should be viewed as specialists in the field. A formal process should be developed to allow close collaboration, coordination and communication between TB controllers and CHCs.

Resources should be mobilized within organized medicine to strengthen skills and increase the effectiveness of PCPs in screening and diagnosing TB. The importance of TB and the critical need to now take action should be emphasized as well. ACET can

take initial steps in this effort by outlining these concerns in a letter to the American Medical Association president and appointing a member of the National Medical Association (NMA) to serve as an ACET liaison representative. ACET made a formal recommendation on the record for CDC to hold a consultation with PCPs and NGOs to explore and enhance mechanisms to improve capacity to diagnose and follow up persons at risk for TB. No members opposed the formal recommendation.

### Update on the Revised TB Infection Control Guidelines

Dr. Paul Jensen of DTBE reported on the progress made since the previous ACET meeting in revising the 1994 TB infection control guidelines for health care facilities. NCHSTP received preliminary clearance to distribute the document to ACET and the Healthcare Infection Control Practices Advisory Committee (HICPAC) only. Eleven reviewers from the two groups submitted >200 specific comments and several general comments through September 11, 2003. The major format changes of the revised 155-page document include 13 sections, additional references and nine supplements.

Whenever possible, the language was revised in response to recommendations by ACET and HICPAC that certain terms be clarified. For example, all settings should conduct "regular, periodic" TB risk assessments was changed to "initial and ongoing." Sections that only mentioned "TST" were expanded to include "tests for *Mycobacterium tuberculosis* infection." Specific language for TST and the QFT-TB test was added if defined policies exist. The ninth supplement is devoted to the QFT-TB test. As information becomes available on new generations of the test, an erratum will be developed for the supplement or *MMWR* articles will inform the reader that the data supercede supplement 9 of the occupational TB infection control guidelines.

The roles of FDA, the National Institute for Occupational Safety and Health (NIOSH), and the Occupational Safety and Health Administration (OSHA) in respiratory protection were more clearly defined. Surgical procedures, the presence of blood-borne pathogens and other appropriate situations for health care workers to wear masks rather than respirators were clarified. Language on special-use respirators is being modified to be more explicit. For example, FDA approves N95-certified respirators as both a surgical mask and respirator. The revised guidelines will not contain a recommendation on using respirators for patients if no masks are available.

Respirators used in the health care field versus those used in industry are compared and contrasted to address real and perceived differences between the two types. The term "periodic fit testing" was not changed, but more details were provided to focus on health care workers who switch to a different respirator model or have a change in physical structure. A response could not be provided to the reviewers' question on

whether data are available to support recommendations on using respirators and surgical masks for TB. Several terms were more clearly defined. "Fit factor" relates to a quantitative test. "Assigned protection factor" (APF) notes OSHA's proposed rule to modify the respirator standard and include APFs for current respirator regulations.

CDC is currently developing a harmonious statement to incorporate into OSHA's public docket. "Well-fitting respirators" are those that inherently fit better than others. NCID recommended adding varicella to the guidelines and de-emphasizing severe acute respiratory syndrome. The transmission route of the disease by air or contact is uncertain at this time. The preamble acknowledges that TB infection control is a component of the overall infection control program in any health care facility. HICPAC recommended that the guidelines be evidence- rather than reference-based.

After the occupational TB infection control guidelines are cross-cleared by five CDC centers, institutes and offices, the draft will be published in the *Federal Register*. Public comments will be addressed and formally evaluated for usability. The draft will be revised based on public comments, resubmitted for CDC clearance and published as an *MMWR R&R*. During this process, CDC will develop supplemental educational materials. The draft is expected to be published in the *Federal Register* by December 1, 2003; the final *MMWR R&R* will be published in 2004.

ACET made several recommendations for CDC to consider before publishing the draft guidelines in the *Federal Register*.

- Use the 1999 Coffey, et al. study as evidence-based data to remove the fit testing recommendation. The findings show that certain masks are superior to others when tested. In general, apply evidence-based data to the guidelines whenever possible.
- Consider revising the guidelines to recommend fit testing for visitors since these persons will provide care after the patient is released from the health care facility.
- Delete rather than define "APF" and "fit factor" from the guidelines.
   Alternatively, provide an explanation to advise practitioners in interpreting fit factor if the term cannot be deleted.
- Use "TBT" as the acronym for the TB blood test.
- Provide health care facilities with an option in the guidelines in which certified fit factor respirators at a certain level would be an alternative to fit testing.
- Format the NCHSTP guideline using a "Rating Scheme for Clinical Practice" based on strength of the recommendation and quality of evidence for the recommendation.

To address ACET's concern with the fit factor language in the guidelines, a formal motion was placed on the floor: "CDC should ensure that the certification process for respirators includes a fit test component and publicly available fit factor rating." ACET's motion is consistent with NIOSH's comments to OSHA on the APF rule-making that fit testing be incorporated into the NIOSH certification process for respirators. The motion was properly moved and seconded by voting members and unanimously passed with no opposition.

### TB Elimination Among U.S.-Born African Americans

<u>DTBE Perspective</u>. Dr. Taylor highlighted DTBE's recent activities in response to recommendations made by the Southeast TB (SETB) Workgroup and attendees at the SETB consultation. First, communication should be maintained with SETB consultation participants. DTBE developed *The TB Challenge: Partnering to Eliminate TB in African Americans* newsletter to highlight issues related to TB among blacks. The publication will also feature activities of different states. The quarterly newsletter will be distributed to SETB consultation attendees, ACET, NCET, TB controllers, and other DTBE traditional partners.

Second, the visibility of the problem with DTBE's traditional and non-traditional partners should be increased. DTBE's article on TB disparities in the Southeastern United States is currently undergoing clearance and will soon be published in the *MMWR*. The article is based on 1991-2001 surveillance data, highlights historically high TB rates among blacks in the Southeastern United States, and suggests that new initiatives are needed to close the gap. DTBE developed a fact sheet template to be used by Southeastern states. Each state can enter site-specific data and then distribute the document to educate policymakers and outside organizations. DTBE is collaborating with NCHSTP to coordinate outreach efforts at minority health meetings.

Third, federal resources should be targeted to address the problem. DTBE will conduct a social science project in Georgia, Mississippi, North Carolina, South Carolina and Tennessee to analyze adherence to treatment for TB and LTBI among blacks. DTBE is conducting a project in Chicago, Georgia and South Carolina to accelerate the decline of TB in blacks. The project areas are developing innovative strategies to address this issue, such as strong linkages with substance abuse treatment facilities; partnerships with faith-based organizations and other non-traditional groups; and close collaborations with CHCs to identify a medical home for TB patients.

DTBE will place a stronger emphasis in the FY'05 cooperative agreement on eliminating the disparity in TB rates among U.S.-born blacks. For example, language in the program announcement can direct each applicant with >50 TB cases in blacks to

include a specific plan to address this issue in the proposal. Grantees can be required to examine and measure program indicators to evaluate programs, such as a comparison with case rates among U.S.-born whites and an assessment of contact investigations by race/ethnicity.

<u>SETB Workgroup Perspective.</u> Dr. Stephanie Bailey is a former ACET member and the SETB TB Workgroup Chair. She made suggestions to maintain the momentum and sustain the focus on TB in U.S.-born blacks. In addition to state activities, the *TB Challenge* newsletter should also highlight projects being conducted by NGOs that attended the SETB consultation. As DTBE redirects targeted testing dollars to Model TB Centers, building linkages with NMA, the National Minority Health Education Network and Training Center, and other medical societies should be a requirement of funding. DTBE should sponsor a large follow-up SETB consultation within the next two years to allow the original participants to describe ongoing activities, lessons learned and accomplishments.

Based on feedback from the SETB consultation participants, CDC should remain involved with this activity. Strong efforts should be made to obtain wider support for the SETB initiative throughout HHS. CHCs will be more likely and willing to partner with SETB project grantees if the HRSA Administrator publicly endorses the activity. *Timebomb* can be used as a resource to assist providers in describing to TB patients to consequences of not adhering to treatment and the process by which the disease consumes the body. The book was written by Dr. Lee Reichman, an ACET liaison representative. Dr. Bailey was extremely excited about the *TB Challenge* newsletter and DTBE's other accomplishments to date.

HRSA committed to providing DTBE with a list of local CHCs. This resource can be distributed to grantees of the project on accelerating the decline of TB in U.S.-born blacks. ACET applauded DTBE on quickly producing the phenomenal and high-quality *TB Challenge* newsletter. DTBE transformed recommendations by the SETB Workgroup and consultation participants into concrete activities. ACET recommended that best practices from DTBE's health disparities projects on TB in blacks be compiled and published. Agreement was reached for ACET to send a brief on this issue to the Congressional Black Caucus and Regional HHS Director of the Southeast. The *TB Challenge* newsletter will be attached to the brief. CDC will provide ACET with technical input in developing the brief as needed.

ACET applauded Dr. Bailey for her outstanding role as the SETB Workgroup Chair and also acknowledged the time, effort and valuable contributions of the members. The SETB Workgroup will complete a final task before disbanding. Dr. Kawamura has drafted a letter to the SETB consultation participants summarizing ACET's activities and outlining the five-point strategy to increase awareness of TB disparities in the

Southeastern United States. The five-point strategy was previously distributed to ACET and approved by the members. Dr. Kawamura will include accomplishments by DTBE and the SETB consultation participants, circulate the final letter to ACET and copy all TB controllers. ACET was extremely pleased that NTCA has formed a workgroup and will maintain the focus on TB in U.S.-born blacks. DTBE pointed out that its inability to expand TB health disparities projects in U.S.-born blacks and Mexican nationals to the entire country is another adverse effect of the inadequate TB budget.

### Strategic Plan for TB Training and Education

Dr. Randall Reves is the ACET liaison for NTCA. He reported that the three Model TB Centers were not established to provide TB training and education for the nation. Instead, the facilities were developed to respond to outbreaks of TB cases and MDR-TB in certain jurisdictions only. In contrast, the ten regional Model STD Centers throughout the country all perform onsite training and clinical updates. The strategic plan for TB training and education referenced in the IOM report is now being revised by six workgroups. Funding is not available to publish, disseminate and implement the updated strategic plan, but this resource will be critical in the TB elimination effort. For example, no action can be taken on ACET's recommendation to educate PCPs, organized medicine, private-sector physicians and non-traditional partners if TB staff are not trained. Dr. Reves outlined these concerns in a September 26, 2003 letter to the ACET Chair and Executive Secretary.

ACET weighed in the IOM recommendation for CDC to continue funding the TB strategic planning process. DTBE should review education and capacity-building efforts by other CDC divisions for replication in TB. CDC performance standards are distributed to local and state public health departments and applied to routine practice. A periodic review to evaluate implementation of the performance standards is conducted in a process similar to the Joint Commission of Accreditation of Health Organizations. The performance standards are used as a requirement for health departments to obtain federal funding. ACET acknowledged that the absence of a TB prevention and control workforce is another critical training and education need. ACET made a formal statement for the record to support an ongoing strategic planning process for TB training and education that will yield a solid document, identify needs and advocate for resources.

CDC made follow-up remarks to ACET's deliberations. Incorporating mandatory competencies in program announcements is premature for NCHSTP at this point. Similar to health departments and NGOs, the TB strategic planning process is also extremely important to CDC. The original strategic plan led to the development of the

TB Education and Training Network, the listserv of TB education products and resources, the TB searchable database and other key activities.

### **Closing Session**

The next ACET meeting is tentatively scheduled for February 4-5, 2004. DTBE will poll the members by e-mail to confirm this date. There being no further business or discussion, Dr. Kawamura adjourned the ACET meeting at 11:46 a.m. on October 2, 2003.

	I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.
Date	L. Masae Kawamura, M.D., ACET Chair